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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,065	03/19/2001	Joel S. Rossier	JYG106USA	9003
270	7590	12/31/2003		
HOWSON AND HOWSON ONE SPRING HOUSE CORPORATION CENTER BOX 457 321 NORRISTOWN ROAD SPRING HOUSE, PA 19477			EXAMINER MUTSCHLER, BRIAN L	
			ART UNIT	PAPER NUMBER
			1753	

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,065

Applicant(s)

ROSSIER ET AL.

Examiner

Brian L. Mutschler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because it contains legal terminology including the word "said". Correction is required. See MPEP § 608.01(b).
2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The disclosure is objected to because of the following informalities:
 - a. The disclosure includes multiple definitions of the reference signs **4, 5, 6,** and **7**. On page 8 at line 18, the reference signs are defined as positions; on page 9 at lines 1-2, the reference signs are defined as the microchannel network; on page 9 at line 13, the reference signs are defined as inlets and outlets; and on page 12 at line 33, the reference signs are defined as channel openings. Each reference sign should refer only to a single feature of the device.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "the injection step" in line 4. There is insufficient antecedent basis for this limitation in the claim. It appears that step (c) of claim 8 would be the injection step, but there is also a discrepancy in the terminology used; claim 8 recites the pumping of a sample solution, while claim 9 recites the flow of liquid. If step (c) is the injection step, what is the relationship between the sample solution and the liquid?

Claim 10 recites the limitation "wherein pressure is applied only during the injection step" in lines 1-2. As explained above for claim 9, there is insufficient antecedent basis for the limitation "the injection step" in the claim. Additionally, claim 10 appears to conflict with the limitations recited in claim 8. In step (a), pressure is applied; in step (b), pressure is applied; and in step (c), the sample is "pushed", which implies that pressure is also applied. Therefore, it appears that pressure is applied at all steps and that the limitation of claim 10 contradicts the limitations of the claim from which it depends.

Claim 11 recites the limitation "in step 2(c)" in lines 1-2. Claim 8 does not recite a step "2(c)". It appears that the phrase should be changed to "in step (c)".

Regarding claim 11, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey (U.S. Pat. No. 5,858,195) in view of Knapp et al. (U.S. Pat. No. 6,235,471) and in view of Jorgenson et al. (U.S. Pat. No. 5,389,221).

Regarding claim 1, Ramsey teaches a micro-analytical apparatus for manipulating fluid samples comprising a substrate with a covered channel and openings at each of the channels (figs. 1, 2 and 31A-31C). The channels intersect to form a common intersection **40** (figs. 1 and 31A-31C). The electrokinetic valve and flow control system are connected to the end of each channel using electrodes, and the system acts as a valve to selectively control the volume of material transported through the intersection using electrophoretic and electroosmotic flow (col. 4, lines 6-30; col. 9, lines 25-40).

Regarding claim 2, the substrate is made of glass, crystalline quartz, fused quartz, fused silica, plastics, and silicon (col. 8, lines 21-36).

Regarding claim 3, the channels are covered with a cover plate that is bonded by a thermal bonding process (col. 8, lines 44-50). It is noted that the additional structural limitations of claim 3 consist only of a cover over the channels; the method by which the cover is affixed to the substrate does not limit the structure of the device.

Regarding claim 4, as shown in Figure 1, all of the openings at the ends of the channel are connected to the flow control system (fig. 1).

Regarding claim 5, a detection region is located along the channels (col. 10, lines 36-41; col. 16, line 47+).

Regarding claim 6, the detection region consists of electrodes or a window for spectroscopic detection, as evidenced by the fluorescence images shown in figure 8(b) (col. 16, line 47+).

Regarding claim 7, the channels may be attached to a detection device (col. 16, line 47+).

Regarding claim 8, Ramsey discloses a method of manipulating fluid samples in the apparatus comprising the steps of:

- a. Pumping solvent (eluent) from reservoirs **12** and **14** located at the ends of channels **26** and **28** (comprising the first channel with channel **34**) through the intersection **40** while applying pressure to channels **30** and **32** (second channel) (fig. 31C). While it is noted that Figure 31C is the "Finish" of the process as shown in the sequence of the three figures, Ramsey teaches

that the process repeats and injects a second sample as a first sample is in channel **34**, thus making Figure 31C the first step in the manipulation of the second sample.

- b. Switching the control system to a second position so that a sample solution is pumped from the analyte reservoir **16** into channel **30** (second channel) while pressure is applied to the other three openings (fig. 31A).
- c. Switching the control system back to the original position so that the sample is pushed from channel **30** (second channel) through the intersection **40** and along channel **34** (first channel) (fig. 31B).

Regarding claim 9, an electric field is applied in the channels to sustain the flow of liquid during the method (fig. 32).

Regarding claim 10, pressure is applied during the injection step (figs. 31A-31C). It is noted that movement caused by electrokinetic flow is accompanied by a pressure differential.

Regarding claim 11, the sample is pushed using electroosmotic or electrokinetic flow (col. 9, lines 35-40).

The apparatus and method of Ramsey differs from the instant invention because Ramsey does not teach the following:

- a. A multi-port valve, as recited in claim 1. (Ramey teaches an electrokinetic valve.)
- b. The eluent solution is mechanically pumped, as recited in claim 8.

- c. The manipulation of the fluid samples uses steps of switching the multi-port valve, as recited in claim 8.

Regarding claims 1 and 8, Knapp et al. disclose a micro-analytical system and methods for using the systems. Knapp et al. teach that material transport systems for moving fluid samples through microfluidic channels include "electrokinetic, electroosmotic, and electrophoretic systems (e.g., electrodes in fluidly connected wells having a coupled current and/or voltage controller), as well as micro-pump and valve systems" (col. 10, lines 12-19).

Jorgenson et al. teaches a micro-analytical apparatus comprising intersecting channels wherein ends of the channels are connected to a multi-port valve to control the pressure-based flow through the system (figs. 5A and 5B).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the electrokinetic valve in the apparatus of Ramsey, which acts as a valve to control the flow of materials through the intersection, to use a multi-port valve as taught by Jorgenson et al. because Jorgenson et al. and Knapp et al. demonstrate and teach that electrokinetic control systems and multi-port valves are equivalent means to control flow through the intersection of channels in microfluidic devices.

- 8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey (U.S. Pat. No. 5,858,195) in view of Knapp et al. (U.S. Pat. No. 6,235,471) and in view

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of Jorgenson et al. (U.S. Pat. No. 5,389,221), as applied above to claims 1-11, and further in view of Parce et al. (U.S. Pat. No. 6,458,259).

Ramsey, Knapp et al., and Jorgenson et al. describe an apparatus and method having the limitations recited in claims 1-11 of the instant invention, as explained above in section 7.

The apparatus and method described by Ramsey, Knapp et al., and Jorgenson et al. differs from the instant invention because they do not disclose that at least part of the first or second channel contains a stationary phase in order to perform chromatography, electrochemistry, electrophoresis, immunological or enzymatic analysis or any combination thereof, as recited in claim 12.

Parce et al. disclose a micro-analytical apparatus and method using both mechanical and electrical flow through the channels. Parce et al. teach that the channels may optionally contain a gel (stationary phase) (col. 4, lines 38-42).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method described by Ramsey, Knapp et al., and Jorgenson et al. to use a stationary phase as taught by Parce et al. because stationary phase allows for a greater separation in components in electrophoretic separations.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references disclose similar means for controlling the flow of liquids through channels on microfluidic devices.

US 2001/0052460 A1 Chien et al.

US 2002/0166592 A1 Liu et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian L. Mutschler whose telephone number is (571) 272-1341. The examiner can normally be reached on Monday-Friday from 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



blm
December 15, 2003

NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700